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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,934	05/03/2000	ANDREAS STEINMEYER	SCH1747	6707

7590

08/13/2003

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/509,934

Applicant(s)

STEINMEYER ET AL.

Examiner

Sabiha Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 1-3, 5, 6, and 8-35.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-3, 5, 6 and 8-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-3, 5, 6, and 8-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Interview Summary

Application No.

09/509,934

Applicant(s)

STEINMEYER ET AL.

Examiner

Sabiha Qazi

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All participants (applicant, applicant's representative, PTO personnel):

(1) Sabiha Qazi.

(3) _____.

(2) Brion Heaney.

(4) _____.

Date of Interview: 05 August 2003.

Type: a) ☒ Telephonic b) ☐ Video Conference

c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.

If Yes, brief description: _____.

Claim(s) discussed: _____.

Identification of prior art discussed: _____.

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Examiner has called to discuss the possible amendments as claims were being added every time when the response was filed, making the search more complex. Mr. Heaney said he will call back after consulting with the applicants. No call was received therefore, it was decided to restrict the invention.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

DETAILED ACTION

Acknowledgement is made of the response filed in paper no. 22 and IDS filed in paper no. 23. Examiner notes, that this IDS was filed after receiving five actions including final and advisory. Since starting from 13 claims were continuously added making the prosecution more complex. Claims 1-3, 5, 6, and 8-35 are pending. The examiner has called Attorney Brion Heaney to discuss the possible amendments. Mr. Heaney told the Examiner that he will talk to the Inventors and will call back (see the interview summary). No call was received therefore; it was decided to restrict the claims for a possible reasonable search.

Election/Restrictions

This application contains claims 1-3, 5, 6, and 8-35 are directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art.

I. Claims 1-3, 5, 6, 14, 20-28 and 30-35, drawn to vitamin D compounds compositions and their process of making. When R1 and R2 are H, V and W together present a double bond; R3 and R4 represent a H or an alkyl group,

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- II. Claims 1-3, 5, 6, 14, 20-28 and 30-35, drawn to compounds, compositions and their method of making when R1 and R2 are methylene, V and W together present a double bond, R3 and R4 represent a H or an alkyl group.
- III. Claim 8, drawn to method for treating
- IV. Claim 9, drawn to method for treating.
- V. Claim 10 drawn to method for treating.
- VI. Claim 11, drawn to method for treating.
- VII. Claim 19, drawn to specific compound, compositions and their process of making.
- VIII. Claim 29, drawn to method for preparing pharmaceutical composition.
- X. Claims 12 and 13, drawn to intermediate compounds.
- XI. Claim 15, drawn to a method for treating.
- XII. Claim 16, drawn to a method for regulating hair growth.
- XIII. Claim 17, drawn to a method of providing birth control to a male or female.
- XIII. Claim 18, drawn to method of inducing an immuno-stimulant effect.
- XIV. Claims 1-3, 5, 6, 14, 20-28 and 30-35, drawn to compounds, compositions and their method of making when R1 and R2 are methylene, V and W together present a double bond, R3 and R4 represent other than H or an alkyl group.

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XV. Claims 1-3, 5, 6, 14, 20-28 and 30-35, drawn to compounds, compositions and their method of making when R1 and R2 are H, V and W together present a double bond, R3 and R4 represent other than H or an alkyl group.

The inventions are distinct, each from the other because of the following reasons:

The invention of group I, II and III-XV are drawn to structurally dissimilar compounds with different cores and their method of use. Compounds of group I are drawn to vitamin D compounds, their preparation and method of use whereas intermediate compounds of group X are epoxy dioxalane compounds. Similarly the methods of treatment of regulating hair growth are completely different from a method of providing birth control. All the methods as cited group are different and according to PCT rules represent lack of unity of invention.

These groups are separate inventions and are patentably distinct. A reference used to reject invention of group I will not be used to reject the invention of any other group. Similarly in vitamin D art compounds having 19-nor structure, R3 and R4 are H, or alkyl and having double bond in the side chain will be different from the compounds having a 19-methylene group and R3 and R4 other than H or alkyl. Similarly Z and Q are too broad in vitamin D art because a minor change in structure is very significant in this class of compounds.

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Accordingly, unity of invention is lacking and restriction of the invention in accordance with the rules of unity of invention is proper. Applicant is requested to elect a species from the elected group for search purposes.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is 703-305-3910. The examiner can normally be reached on every business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in black ink, appearing to read 'S. Qazi', with a long horizontal stroke extending to the right.

SABIHA QAZI, PH.D
PRIMARY EXAMINER

August 11, 2003